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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,781	02/11/2002	Yao-Sung Chang	U 013872-2	6646

7590 11/03/2003

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,781	CHANG ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on July 7, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 9-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/11/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>202</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the papers filed July 7, 2003. Currently, claims 1-15 are pending. Claims 9-15 have been withdrawn as drawn to non-elected subject matter.

Election/Restrictions

2. Applicant's election without traverse of Group I in the paper filed July 7, 2003 is acknowledged.

The response fails to clarify the status of Claim 15 as requested in the restriction requirement. Claim 15 is drawn to a device of Claim 9. However, Claim 9 is directed to a process. Therefore, it is unclear whether the dependency of Claim 15 is incorrect or whether the preamble of Claim 15 is incorrect. Since the response failed to clarify the apparent confusion, the claim has been treated as depending on Claim 9, such that the preamble is incorrect. Thus, Claims 9-15 have been withdrawn.

Drawings

3. The drawings are acceptable.

Specification

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The instant abstract contains several legal phraseology which should be avoided, namely "said." Moreover, the first phrase is "the invention discloses."

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-8 are indefinite over the recitation "said fluid element" in line 7 of Claim 1. "Said fluid element" lacks proper antecedent basis. While the claim refers to a fluid driving element, the claim fails to specifically point out a fluid element. The claim may be easily amended to recite "said fluid driving element."

B) Claim 8 is directed to the device of Claim 1 which can be used in removing the target molecules non-specific binding to said probes. It is unclear whether the claim is intended to encompass an additional component to the device which can remove non-specific binding probes or whether the claim is merely reciting that the device can remove the non-specific target molecules. In the former case, the claim appears to be missing words. In the later case, the claim does not appear to further limit the device as

set forth in Claim 1. There would be no additional components and thus, would not further limit the device of Claim 1. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-8 are rejected under 35 U.S.C. 102(a) and 102 (e) as being anticipated by Knapp et al. (US Pat. 6,235,471, May 2001).

Knapp et al. (herein referred to as Knapp) teaches a device for hybridization which comprises a microfluidic channel comprising a first and second portion, an irregular cross section and a second portion with a probe, and a driving element. Specifically, Knapp teaches a microfluidic system which has at least a first reaction channel and at least a first reagent introduction channel (col. 5, lines 5-10). Knapp teaches fluid can flow between the channels with a material transport system which may include micropumps, microvalves, fluid switches, for example (col. 5, lines 20-25)(limitations of Claim 1b). Knapp teaches that the reagent channel is a channel in any form such as a capillary, a trench, groove or the like (col. 10, lines 5-8)(limitations of

Claim 3). Knapp teaches that “as fluid moves through a structure of varying cross sectional areas, its temperature will change, depending on the dimensions of the channel at any given point (col. 19, lines 60-65)(limitations of Claim 7). Knapp teaches that “a number of different channel geometries are effective in producing the nonthermal amplification devices and systems of the present invention” (col. 23, lines 36-41).

Knapp teaches a device fabricated into a solid substrate that includes a main analysis channel which comprises hybridization sites. The device also contains reservoirs connected by intersecting channels. Knapp teaches that when samples are double stranded genomic DNA, the sample may be denatured in a reservoir and moved into the main analysis channel (col. 32, lines 25-45). The reservoir and channel intersections comprise a widened channel, i.e. an irregular cross section, to facilitate mixing of the sample (col. 32)(limitations of Claim 1b, 2). The immobilization of oligonucleotides on solid substrates is carried out by any of a variety of methods (col. 32, lines 50-53)(limitations of Claims 4, 5, 6). Knapp teaches that sequential purification of the target portion of the genome can be achieved by selective hybridization (col. 33)(limitations of Claim 8). The non-hybridized DNA is washed out of the main analysis channel (col. 34). Knapp teaches that in order to maximize the use of space on a substrate, serpentine, saw tooth or other channel geometries are used to incorporate longer channels on less substrate area to facilitate separation of reaction products or reactants (col. 42, lines 5-10). Knapp teaches that microfluidic devices are employed such that they utilize less space, have smaller reagent requirements, automatable which

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allows less human involvement and reduces error, contamination, and loss of material
(col. 12, lines 20-30).


Conclusion

7. No claims allowable over the art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jeanine Goldberg
Patent Examiner
October 30, 2003